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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,688	12/20/2001	Osamu Asano	0425-0867P	7785

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,688

Applicant(s)

ASANO ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-35 and 37-48 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 22-25 and 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16-21, 26 and 35 is/are rejected.
- 7) ☒ Claim(s) 37-48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 11.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' communication paper #10 dated 9/29/03 is acknowledged. Applicants have cancelled claims 13,36, amended claims 1-12, 14-19, 20,21,23,25,34,35, and added new claims 37-48. Claims 14,15,22,23,24,25,27-34 are withdrawn from consideration as per earlier Office Communication paper #9 dated 6/27/03, and this communication. 37 CFR 1.142(b). See also interview summary, enclosed as paper # 11 with this communication. Therefore, the claims under consideration are the claims 1-12,16-19,20,21,26,35,37-48. The restriction requirement is made FINAL.

Upon further review and consideration, this application is not found ready for allowance as a single piece after rejoining all of the inventions for the reasons stated below.

Election/Restrictions

1. Applicant's election with traverse of invention of Group I, and the species of Example 46 wherein both W and Q are nitrogen i.e. purine core in Paper No. 10 dated 9/29/03 is acknowledged. The traversal is on the ground(s) that different structures as outlined in earlier office communication are not the basis for "special technical features" as per PCT Rules.

It appears that the applicants have not reviewed the interview summary also listed as paper # 9. The typo-error of not citing the same in earlier office communication paper #9 is regretted.

Therefore, applicants' arguments are not believed to be correct and their reasons for rejoining of various groups are not found persuasive for the inventions listed

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as Groups I-IV. They do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They have different chemical structures. The claims lack unity of invention because compounds of Formula (I) do not possess single structural element that is shared by all of the alternatives. The only common technical feature shared by all of the alternatives of the Formula (I), namely, 1,3-diazole ring fused to either a six membered phenyl or a non-aryl ring consisting of pyridine or pyrimidine cores(= imidazole fused to a heterocycle), is old. The common structural feature of Formula I is not a patentable advance(s) over the prior art(s).

For applicants' quick reference "Unity of Invention rule 37 CFR 1.475" is recited below:

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a

group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention "). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

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(C). If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Examiner has considered (b) (3) and (C). of above guidelines as per rule 37 CFR 1.475 for the restriction/election of this application as stated above.

Following different cores are formed for the variables recited in the instant generic as well as independent claims. Examiner did perform initial search and examination wherein following hits were obtained:

- 1). Purine core, when Q & W = Nitrogen, classified in class 544, subclasses 253,255,256,264,265,277, total hits obtained were: 1619;
- 2). Pyridine-imidazole core when one of W/Q = Nitrogen, classified in class 546, subclasses 112,113,118, total hits obtained were: 1655;
- 3). Benz-imidazole core when both of Q,W are carbons, classified in class 548, subclasses 300.1, 302.7,304.4, total hits obtained were: 807;
- 4). Intermediates based on monocyclic pyridine core, classified in class 546, subclasses 261, 262, 264, 265, 304, 347, totals hit obtained were 1488, when one of Q,W is Nitrogen;
- 5). Intermediates base on monocyclic pyrimidine core, classified in class 544, subclasses 242,298,297,322, 323, total hits obtained were 2489;
- 6). There will be additional search for the utility class 514 which will add to the above hits. e.g. only for purine invention, falling in class 514, subclasses 263.4,263.1,263.22, total hits obtained were: 312.

Therefore, examiner decided to limit the search to invention of Group I related to purine core, which involved a total of $1619 + 312 = 1931$ hits.

Rejoining of inventions at this stage will involve additional thorough search for the inventions of Groups II-IV, and the same will require more time, and that is burdensome to examiner within the time limit provided to examine a single application.

Rejoining of the inventions will additionally, raise various unforeseen issues related to patentable distinction. See copy of the CAS/STN search references: McAfee et al (U.S.P. 5117830 also cited as CAPLUS DN 120: 95745(=CAS RN 131713-84-3)); Barlin et al (CAPLUS DN 75:62924 related to conjugate monoacid(= CAS RN

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33614-05-0); hexachloroplatinate(= CAS RN 33615-92-8); monopicrate(=CAS RN 33631-18-4)); Chin et al (CAPLUS DN 95:6196(=CAS RN 77071-06-8). These are a few of several hits related to the subject matter which constitutes the non-elected subject matter.

Thus, the claims are drawn to structurally dissimilar compounds, which are classified separately, require separate literature searches for the subclasses, and are not art recognized equivalents. They are made and used independently. Each core will require separate search, and additionally as stated earlier, the utility class will constitute different class(es), which will be time consuming and burdensome to examiner.

Applicants have elected invention of Group I with the species of Example 46 as already stated above. Since claims 1-12, 16-19, 20-21, 23, 25, 34, 35, 37-48 link with other inventions examiner has searched the same bearing in mind the elected subject matter as per invention of Group I and species of Example 46 wherein both Q, W are Nitrogen atoms only.

As already stated in earlier office action paper # 9 dated 6/27/03, examiner has followed the election of species guidelines provided in MPEP 803.02 for the examination of this application.

Note that compounds, corresponding compositions, a method of use and a process of making by the first recited process that are of the **same scope** are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.47(d). The scope that a prior art anticipating one compounds under 35 U.S.C. 102 would not render obvious another compound of the same claim under 35 U.S.C. 103.

Applicants were informed about the scope of claims examined so far by the examiner, and in order to further the prosecution, this communication will indicate the allowable subject matter. See interview summary enclosed with this paper.

This application has been found to contain more than one invention. Therefore, the restriction/election requirement is still deemed proper and is therefore now made FINAL.

2. **Rejections withdrawn for subject matter related to elected invention of Group I i.e. purine core only:**

2.1. **Rejections made under 35 U.S.C. 102(a)/(b):** Applicants have amended claims 1-12, 16-19, 20, 21, 26, 35 as stated above to delete the overlapping subject

matter, and also to present the novelty in a clearer manner. However, these claims do include non-elected subject matter. Therefore, rejections made under 35 U.S.C.

102(a)/(b) are now withdrawn for subject matter of invention of Group I invention only.

2.2 Rejections made under 35 U.S.C. 112 paragraph second: Rejection (A) for claims 1-12 related to invention of Group I only is withdrawn as applicants have amended the claims as required by prior the office action paper # 9.

2.3. Rejections made under 35 U.S.C. 101: Applicants have cancelled claim 36, thus the rejection is made moot, and the same is now withdrawn.

3. Rejections maintained:

3.1. Rejection (B) made under 35 U.S.C. 112 paragraph second for claim 20 is maintained further for the reasons already stated in earlier office communication. The claims is related to a compound of claim 1 which has a definite structure. Defining a compound by its biological or a physiological property without a structure is not an exact and definite way. Applicants are required to recite the exact core of elected invention of Group I which is a purine nucleus. See allowable subject matter as stated below.

3.2. Rejections made under 35 U.S.C. 112 paragraph first: Rejections for claims 16-19, 35 are maintained further for the "prevention of diseases" as recited therein for the reasons already state in earlier office communication paper # 9 dated 6/27/03.

Applicants are urged to refer to MPEP 2107.03 for the utility requirement under 35 U.S.C. 112, first paragraph, in drug cases.

Examiner appreciates for the literature reference provided to support the method of use for the instant compounds.

The reference does not deal with the chemical compounds having similar structure(s). e.g. New England J. Med., 339/14, 977-91(1991)) deals with subject matter different chemistry which are not in any way similar to instantly claimed compounds which have a core:"5-[6-amino-8-(3-fluorophenyl)-9H-9-puriny]-1-methyl-1,2-dihydro-2-pyridinone". Therefore, there is no evidence of structural similarity to a ref. compound(s) known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for instantly claimed new compounds. In re. Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). MPEP 2103.03.

Applicants state that the Specification on pages 58-62 recite tests and assays carried out for the instant compounds, demonstrated that the compounds/products of the instant invention can be used for the prevention of a disease. This is not the exact test/assay for ascertaining the therapeutic utility for Humans. Also, Table 1 on page 62 recites test result for a single compound, namely Example 5 which is HCL salt. There is not comparison with the instant species of Example 46 which is a di-hydrate, and as well as art recognized reference.

The expressions "biological activity" and "biological properties" are too nebulous to meet the requirements of 35 U.S.C. 112. In re Kirk et al. (CCPA 1967) 376 F2d 936, 153 USPQ 48. The "how to use" requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Diedrich (CCPA 1963) supra; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

Applicants attention is drawn to the fact that a disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. In re Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974). See also MPEP 608.01(p).

The method of use claims 16-19,35 do not represent exactly a single specific organ related disease in a subject, which could be a human being.

4. New Rejections:

Claims 1-12,21,26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites components R3 and Ar as “optionally substituted heteroaryl group”. The claim does not exactly say about the nature and make up of the heteroatoms, size of the ring, and exact point of attachment with the carbon atom of the main core. Are partially saturated and fully saturated heterorings excluded from the claim?

Claim Objection

5. Claims 37-48 are objected to because of the following informalities: The claims are dependent of rejected claims. Appropriate correction/cancellation is required.

6. Claims 14,15,22,23,24,25,27-34 are objected to because of the following informalities: The claims represent non-elected and non-related subject matter of invention of Group I. In view of allowable subject matter as stated bellow, cancellation is required.

Conclusion

7. ***Allowable Subject Matter***

Claims 1-12,21,26 related to compounds, simple composition, and a process of making of the elected subject matter of invention of Group I would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, objections, and other rejections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The closest prior art ref. Verlinde et al (J. Med. Chem. 37/21, 3605-13(1994)) teaches compounds having a core:"Adenosine, 8-phenyl(CAS RN 73340-78-0); Adenosine, 8-thienyl(CAS RN 158555-06-7)". Verlinde does not indicate or suggest to arrive at the compounds of amended claims related to subject of elected invention of Group I .

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

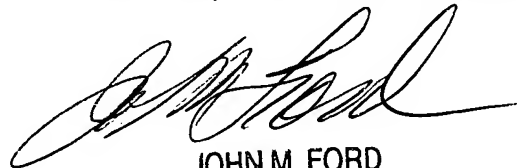
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

Sudhaker B. Patel, D.Sc.Tech.
November 13, 2003.



JOHN M. FORD
PRIMARY EXAMINER

GROUP - ART UNIT 1624



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